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(54) p-MENTHANE DIOLS AND COMPOSITIONS CONTAINING THEM

(71) We, WILKINSON SWORD LIMITED, a British Company, of Sword Works, Southfield Road, London W.4., do hereby declare the invention for which we pray
 5 that a patent may be granted to us, and the method by which it is to be performed to be particularly described in and by the following statement:—

- Field of Invention
 10 This invention relates to compositions having a physiological cooling effect on the skin and on the mucous membranes of the body particularly those of the nose, mouth, throat and gastrointestinal tract.
- Background of the Invention
 15 Menthol is well known for its physiological cooling effect on the skin and mucous membranes of the mouth and has been extensively used as a flavouring agent (menthol being a major constituent of oil of peppermint) in food-stuffs, beverages, dentifrices, mouthwashes, etc. and as a component in a wide range of toiletries, liniments and lotions for topical application. Menthol is also a well known tobacco additive for producing a "cool" sensation in the mouth when smoking.
 20 It is well established that the "cooling" effect of menthol is a physiological effect due to the direct action of menthol on the nerve endings of the human body responsible for the detection of hot or cold and is not due to latent heat of evaporation. It is believed that the menthol acts as a direct stimulus on the cold receptors at the nerve endings which in turn stimulate the central nervous system.
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- Although menthol is well established as a physiological coolant its use, in some compositions, is circumscribed by its strong minty odour and its relative volatility.
- Objects of the Invention
 40 It is an object of the present invention to provide ingestible, topical and other compositions capable of stimulating the cold receptors of the nervous system of the human body thereby to create a desirable cool sensation.
- 45 A further object is to provide a method of stimulating the cold receptors of the nervous system of the human body to create a desirable cool sensation.
- Summary of Invention
 50 The present invention is based on the discovery that certain *p*-menthane diols have a pronounced physiological cooling effect but little or no odour.
- 55 The invention therefore provides compositions, in particular ingestible compositions and compositions for topical application, capable of stimulating the cold receptors of the nervous system of the human body comprising an effective amount of a cold receptor stimulant and a vehicle therefor, the stimulant comprising one or more *p*-menthane diols having the hydroxy substituents on different carbon atoms and one of the hydroxy substituents, at least, being in the 2- or 3-position.
- 60 Particular compositions provided within the scope of this invention are:
- 65 1) Comestible compositions comprising an edible base, a flavourant or colourant, and a cold receptor stimulant as defined above.

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	2) Beverages comprising a potable base, a flavourant or colourant, and a cold receptor stimulant as defined above.	60
5	3) Lotions comprising an aqueous, alcoholic, or aqueous-alcoholic carrier, an adjuvant selected from the following: a colourant, an antiseptic or an odourant, and a cold receptor stimulant as defined above.	65
10	4) Dentifrices comprising an abrasive, a detergent or foaming agent and a cold receptor stimulant.	70
15	5) Toilet preparations, e.g. soaps and creams, comprising an oleaginous base and a cold receptor stimulant as above defined.	75
20	6) Pharmaceutical preparations comprising an antacid and a cold receptor stimulant as above defined.	80
25	7) Toilet articles, e.g. cleansing tissues and toothpicks, comprising a carrier impregnated or coated with one or more of the specified diols.	85
30	8) Articles and compositions for chewing, smoking or inhaling comprising a tobacco preparation and one or more of the specified diols.	90
35	9) Tobacco smoke filters comprising a fibrous or porous filter impregnated with one of the specified diols.	95
	Detailed Description.	
30	The <i>p</i> -menthane diols used in this invention are known <i>per se</i> . The preferred diols are:	
	2,3- <i>p</i> -menthane diol	
	2,6- <i>p</i> -menthane diol	
	2,5- <i>p</i> -menthane diol	
35	3,5- <i>p</i> -menthane diol	
	3,9- <i>p</i> -menthane diol	
40	The compounds used as cold receptor stimulants in accordance with this invention exhibit both geometric and optical isomerisation and, depending on the starting materials and the methods used in their preparation the compounds may be isomERICALLY pure, i.e. consisting of one geometric or optical isomer, or they may be isomERIC mixtures, both in the geometric and optical sense.	100
45	The cold receptor stimulants used in this invention find utility in a wide variety of compositions for consumption by or application to the human body. Broadly speaking, these compositions can be divided into comestible and topical compositions, both terms being taken in their broadest possible sense. Thus comestible is to be taken as including not only foodstuffs and beverages taken into the mouth and swallowed, but also other orally ingested compositions taken for reasons other than their nutritional value, e.g. indigestion tablets, antacid preparations, laxatives etc. Comestible compositions are also to be taken	105
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	In most compositions according to the invention the vehicle will be or contain one or more of the following: an antacid, antiseptic or analgesic, a flavourant, colourant, or odourant, or a surfactant.	
	The following illustrate the range of compositions into which the <i>p</i> -menthane diols can be incorporated:	120

	1. Edible or potable compositions including alcoholic and non-alcoholic beverages; confectionery, chewing gum, cachous; ice creams; jellies;	in the range 0.05 to 10% by weight based on the total composition.	60
5	2. Toiletries including after shave lotions, shaving soaps, lipstick, creams and foams, toilet water, deodorants and antiperspirants, "solid colognes", toilet soaps, bath oils, and salts, shampoos, hair oils, talcum powders, face creams, hand creams, sunburn lotions, cleansing tissues, dentifrices, toothpicks, mouthwashes, hair tonics, eyedrops;	Because of the cooling sensation imparted to the skin, a major utility of the <i>p</i> -menthane diols will be in a wide range of toilet preparations. The particular preparations discussed below are to be taken as exemplary.	65
10	3. Medicaments and allied compositions including antiseptic ointments, pile ointments, liniments, lotions, decongestants, counter-irritants, cough mixtures, throat lozenges, antacid and indigestion preparations, oral analgesics;	A major utility will be in after shave lotions, toilet water etc., where the compound will be used in alcoholic or aqueous alcoholic solution, such solutions usually also containing a perfume or mild antiseptic or both. The amount of compound added to the formulation will usually be in the range 1.0 to 12.0% by weight based on the total composition.	70
15	4. Tobacco preparations including cigars, cigarettes, pipe tobacco, chewing tobacco and snuff; tobacco smoke filters, especially filter tips for cigarettes;	A further field of utility will be in soaps, shampoos, bath oils etc. where the compounds will be used in combination with an oil or fat or a natural or synthetic surfactant e.g. a fatty acid salt or a lauroylsulphate salt, the composition usually also containing an essential oil or perfume. The range of soap compositions will include soaps of all kinds e.g. toilet soaps, shaving soaps, shaving foams etc. Usually the compound will be added to the formulation in amount of from 5.0 to 16.0% by weight.	75
20	5. Miscellaneous compositions such as water soluble adhesive compositions for envelopes, postage stamps, adhesive labels etc.	Another field of utility will be in cosmetics, such creams and emollients, usually comprising a base emulsion and optionally a range of ingredients such as wax, preservative, perfume, antiseptics, astringents, pigments etc. Once again the formulation of such compositions, apart from the incorporation of the <i>p</i> -menthane diol, usually in an amount of from 0.10 to 20.0% by weight, is conventional.	80
25		A further class of toilet composition into which the <i>p</i> -menthane diols may be incorporated includes cosmetic creams and emollients, such creams and emollients usually comprising a base emulsion and optionally a range of ingredients such as wax, preservative, perfume, antiseptics, astringents, pigments etc. Once again the formulation of such compositions, apart from the incorporation of the <i>p</i> -menthane diol, usually in an amount of from 0.10 to 20.0% by weight, is conventional.	85

Particular preparations according to the invention are discussed in more detail below:

Edible and Potable Compositions.

	The edible and potable compositions of this invention will contain the <i>p</i> -menthane diols in combination with an edible carrier and usually a flavouring or colouring agent. The particular effect of the <i>p</i> -menthane diols is to create a cool or fresh sensation in the mouth, and in some cases, even in the stomach, and therefore the compounds find particular utility in sugar-based confectionery such as chocolate, boiled sweets, mints and candy, in ice cream and jellies and in chewing gum. The formulation of such confections will be by ordinary techniques and according to conventional recipes and as such forms no part of this invention. The <i>p</i> -menthane diols will be added to the recipe at a convenient point and in amount sufficient to produce the desired cooling effect in the final product. As already indicated, the amount will vary depending upon the particular compound, the degree of cooling effect desired and the strength of other flavourants in the recipe. For general guidance, however, amounts in the range 0.1 to 10% by weight based on the total composition will be found suitable.	Compositions for oral hygiene to which the <i>p</i> -menthane diols may be added include mouthwash, gargle and dentifrice compositions. The first two may be considered together and will usually comprise an aqueous, alcoholic or aqueous-alcoholic solution of an antiseptic often coloured or flavoured for palatability, to which <i>p</i> -menthane diol is added in an amount of from 0.10 to 2.0% by weight.	90
30		Dentifrice compositions may be of the solid block, powder, paste or liquid type and will usually comprise a finely divided abrasive or polishing material, e.g. precipitated chalk, silica, magnesium silicate, aluminium hydroxide or other similar materials well known in the art, and a detergent or foaming agent. Optional ingredients which may also be included are flavouring agents and colourants, antiseptics, lubricants, thickeners, emulsifiers or plasticizers. A typical toothpaste formulation to which the <i>p</i> -menthane diol may be added to give a fresh, cool sensation in the mouth, consists of:	95
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Similar considerations apply to the formulation of beverages. Generally speaking the compounds will find most utility in soft drinks e.g. fruit squashes, lemonade, cola etc., but may also be used in alcoholic beverages. The amount of compound used will generally be

Ingredient	% by weight
Precipitated chalk	20
Fine Silica	15
Magnesium carbonate	4
Dicalcium Phosphate	6
Surfactant e.g. alkylated aryl sulfonate	8
Starch glycerite	18
Mineral Oil	1
Mucilage	4
Syrup	12
Glycerin	12

5 The amount of *p*-menthane diol added in such compositions will generally be from 1.0 to 4.0% by weight based on the total compositions.

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Medicaments.

Because of their cooling effect on the skin and on the mucous membranes of the mouth, throat and nose and of the gastrointestinal

10 tract the *p*-menthane diols may be used in a variety of oral medicines, nasal and throat sprays, and topical compositions, particularly where a counter-irritant is required. In particular the compounds may be formulated into antacid and indigestion remedies, in particular those based on sodium bicarbonate, magnesium oxide, calcium or magnesium carbonate, aluminium or magnesium hydroxide or magnesium trisilicate. In such compositions the compound will usually be added in an amount of from 0.10 to 2.0% by weight.

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15 The *p*-menthane diols may also be included in oral analgesic compositions e.g. with acetyl salicylic acid or its salts, and in nasal decongestants e.g. those containing ephedrine.

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Tobacco Preparations

The coolants used in this invention may be incorporated directly into tobacco to give a cool effect when smoking but without the attendant strong and characteristic odour which is associated with mentholated tobacco and cigarettes. Such compositions also have considerable storage stability, which is in contrast to mentholated products. However, a more advantageous utilisation is in pipe or

cigarette filters, in particular, filter tipped cigarettes. The pad of filter material, which may be of any of the well known types, e.g. cellulose acetate, paper, cotton, α -cellulose or asbestos fiber, is simply impregnated with an alcoholic solution of the coolant dried to deposit the coolant in the filter pad. The effect is to give a pleasant cool sensation in the mouth when the cigarette is smoked. As little as 0.02 mg. of the coolant is effective.

Compounds and compositions of this invention are illustrated by the following Examples.

Example I

Aerosol Shaving Soap

An aerosol shaving soap composition was formulated according to the following recipe:

Stearic acid	6.3%
Lauric acid	2.7
Triethanolamine	4.6
Sodium carboxymethyl cellulose	0.1
Sorbitol	5.0
Perfume	0.4
Water	to 100%

The composition was prepared by fusing the acids in water, adding the triethanolamine, cooling and adding the other constituents. To the mixture was then added 12.0%, based on the total composition, of 2,5-*p*-menthane diol. The composition was then packaged in an aerosol dispenser under pressure of a butane propellant.

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When used in shaving a fresh cool sensation was distinctly noticeable on the face.

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Example II**After Shave Lotion**

5 An after shave lotion was prepared according to the following recipe by dissolution of the ingredients in the liquid and cooling and filtering:

10	Denatured Ethanol	75%
	Diethylphthalate	1.0
	Propylene Glycol	1.0
	Lactic Acid	1.0
	Perfume	3.0
	Water	to 100%

15 Into two separate samples of the base lotion were added 5.0% by weight based on the total composition of 2,5-p-menthane diol and 2,3-p-menthane diol, each into a different one of the two samples.

20 When applied to the face a clearly noticeable cooling effect became apparent after a short interval of time.

Example III**Toilet Water**

A toilet water was prepared according to the following recipe:

25	Denatured ethanol	75.0%
	Perfume	5.0%
	Water	to 100%

30 To the recipe was added 5.0%, based on the total composition, of 2,6-p-menthane diol.

35 As with the after shave lotion, a cooling effect was clearly noticeable on the skin well after the termination of any cooling effect attributable to the evaporation of the alcoholic carrier.

Example IV**Deodorant Composition**

40 A deodorant composition suitable for formulation and dispensing as an aerosol under pressure of a suitable propellant was formulated according to the following recipe:

Denatured ethanol	96.9%
Hexachlorophene	2.0%
Isopropyl myristate	1.0%
Perfume	0.1%

45 To the composition was added 6.0% by weight of 2,3-p-menthane diol. Application of the final composition gave rise to a definite cooling sensation on the skin.

Example V**Hair Shampoo**

Sodium lauryl ether sulphate, 10 g., was dispersed in 90 g. water in a high speed mill. To the dispersion was added 8.0% by weight of 3,5-p-menthane diol. When the hair is washed using the shampoo a fresh, cool sensation is noticed on the scalp.

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Example VI**Eye Lotion**

An eye lotion was prepared containing the following ingredients:

Witch Hazel	12.95%
Boric Acid	2.00
Sodium Borate	0.50
Allantoin	0.05
Salicylic Acid	0.025
Chlorobutol	0.02
Zinc Sulphate	0.004
Water	to 100%

To the formulation was added 0.015%, based on the total composition of 2,5-p-menthane diol. When used to bathe the eyes a cool fresh sensation is apparent on the eyeball and eyelids.

Example VII**Mouthwash**

A concentrated mouthwash composition was prepared according to the following recipe:

Ethanol	3.0%
Borax	2.0
Sodium bicarbonate	1.0
Glycerol	10.0
Flavourant	0.4
Thymol	0.03
Water	to 100%

To the composition was added 2.0% of 2,3-p-menthane diol.

When diluted with approximately 10 times its own volume of water and used to rinse the mouth a strong and long lasting cooling effect is obtained in the mouth.

Example VIII**Toothpaste**

The following ingredients were mixed in a blender:

Dicalcium phosphate	48.0%
Sodium lauryl sulphate	2.5
Glycerol	24.8
Sodium carboxymethyl cellulose	2.0
Citrus flavourant	1.0
Sodium saccharin	0.5
Water	to 100%

Shortly before completion of the blending operation 4.0% by weight of 2,5-p-menthane diol was added to the blender.

When applied as a toothpaste, a strong cooling effect is noticed in the mouth.

Example IX**Toothpicks**

The tip of a wooden toothpick was impregnated with an alcoholic solution containing 2,5-p-menthane diol in sufficient amount

to deposit on the toothpick 0.2 mg. of the diol. The impregnated toothpick was then dried. When placed on the tongue there is no detectable taste, however, a distinct cooling effect is noticeable after a short period of time.

Example X

Soft Drink

A soft drink concentrate was prepared from the following recipe:

10	Pure orange juice	60%
	Sucrose	10
	Saccharin	0.2
	Orange flavouring	0.1
	Citric acid	0.2
15	Sulphur dioxide	trace amount
	Water	to 100%

To the concentrate was added 0.5% of 2,3-*p*-menthane diol.

The concentrate was diluted with water and tasted. An orange flavour having a pleasantly cool after-effect was obtained.

Example XI

Boiled Sweet

99.5% sucrose and 0.5% citric acid were carefully fused together in the presence of a trace of water. Just before casting the melt onto a chilled plate 2.5% of 3,5-*p*-menthane diol was rapidly stirred in. The melt was then cast. A boiled sweet resulted having a marked cooling effect on the mouth.

Example XII

Mint Sweet

Water was added to icing sugar at 40° C to form a stiff paste. 2.5% of 2,5-*p*-menthane diol was then stirred into the paste and the mixture allowed to set. A soft sweet mass resulted having the characteristic cooling effect in the mouth of peppermint but without the minty flavour or odour.

Example XIII

Chewing Gum

Leaves of a proprietary chewing gum were leached in running water for 168 hours to remove all water-soluble flavourants. At the end of the leaching operation the chewing gum base had no detectable minty odour or flavour. The chewing gum base was then kneaded with 0.8% of 3,5-*p*-menthane diol. When compared with the water-extracted chewing gum base, the final product showed no distinguishable change in flavour but showed a marked cooling effect in the mouth.

Example XIV

Cigarette Tobacco

55 A proprietary brand of cigarette tobacco was sprayed with an ethanolic solution of 2,5-*p*-menthane diol and was rolled into cigarettes each containing approximately 40 micrograms

of active compound. Smoking the impregnated cigarettes produced a cool effect in the mouth characteristic of mentholated cigarettes but without any attendant odour other than that normally associated with tobacco.

Example XV

Filter Tip Cigarettes

The filter tip of a proprietary brand of cigarette was impregnated with an ethanolic solution of 2,3-*p*-menthane diol in an amount sufficient to deposit in the filter 0.02 mg. of the active compound. Smoking the cigarette with the impregnated tip gave rise to a noticeable cooling effect in the mouth.

Example XVI

Indigestion Tablet

The following ingredients were ground together:

Magnesium Carbonate	49.5%
Sorbitol	49.4%
Saccharin	0.1%
Talc	1.0%

Added to the mixture during grinding was 2.5% of 2,3-*p*-menthane diol. After mixing, the mixture was pressed into 0.5 g tablets.

Taken by mouth and swallowed the tablets produce after a short interval of time a noticeable cooling effect in the stomach.

Example XVII

Antiseptic Ointment

An ointment was prepared according to the following formulation:

Cetyltrimethyl ammonium bromide	4.0%
Cetyl Alcohol	6.0%
Stearyl Alcohol	6.0%
White Paraffin	14.0%
Mineral Oil	21.0%
Water	to 100%

The ingredients were mixed, warmed to 40° C and emulsified in a high speed blender. Added to the mixture during blending was 5.0% of 3,9-*p*-menthane diol.

The final ointment when applied to the skin gave rise to a marked cooling effect.

Example XVIII

Antipruritic Ointment

The following ingredients were warmed together to form a homogeneous melt:

Methyl salicylate	50.0%
White Beeswax	25.0%
Anhydrous lanolin	25.0%

To the melt was added 2.5% of 2,6-*p*-menthane diol and the mixture then allowed to solidify. A soft ointment result having a sooth-

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ing effect on the skin accompanied by a noticeable cooling effect.

Example XIX

Analgesic Tablet

- 5 Soluble aspirin (calcium acetylsalicylate) tablets were impregnated with 0.5% of 2,3-*p*-menthane diol by absorption in the tablet of a metered drop of an ethanolic solution of the diol. When a tablet was swallowed a quite noticeable cooling effect developed in the stomach after a short interval.

Example XX

Cleansing Tissue

- 15 A cleansing liquid was prepared having the formulation:

Triethanolamine Lauryl Sulphate	1.0%
Glycerol	2.0%
Perfume	.95%
Water	to 100%

- 20 To this liquid was added 1.0% of 2,5-*p*-menthane diol. A paper tissue was then soaked in the liquid.

- When the impregnated tissue was used to wipe the skin a fresh cool sensation developed 25 on the skin after a short interval.

Example XXI

Water Soluble Adhesive

- A solution was made up containing 5% gum acacia in water. To this solution was added 30 1.0% of 3,9-*p*-menthane diol. The solution was then coated on a label and allowed to dry. Licking the label to regain the tack prior to affixing the label to a substrate gave a pleasant cooling sensation on the tongue.

- The above Examples illustrate the range of 35 compounds and the range of compositions included within the present invention. However, they are not to be taken as limiting the scope of the invention in any way.

- As the *p*-menthane diols used in the present 40 invention are known compounds, we make no claim herein to the compounds per se, nor do we claim simple solutions of such compounds in water or common organic solvents.

Subject to the foregoing disclaimer WHAT WE CLAIM IS:—

- 45 1. A composition capable of stimulating the cold receptors of the nervous system of the human body, comprising an effective amount of a cold receptor stimulant and a vehicle therefor, said stimulant comprising one or more *p*-menthane diols having the hydroxy substituents on different carbon atoms and one of the hydroxy substituents, at least, being in the 2- or 3-position.
- 50 55 2. An ingestible composition capable of stimulating the cold receptors of the nerve

endings of the mouth and gastrointestinal tract comprising an edible carrier and an effective amount of a cold receptor stimulant as defined in claim 1.

60 3. A composition for topical application to the human body and capable of stimulating the cold receptors of the nerve endings in the skin, comprising a pharmaceutically acceptable carrier and an effective amount of a cold receptor stimulant as defined in claim 1.

65 4. A cleansing tissue comprising a fibrous carrier impregnated with a liquid containing an effective amount of a cold receptor stimulant, said stimulant comprising one or more *p*-menthane diols as defined in claim 1.

70 5. A tobacco smoke filter comprising a filter pad impregnated with an effective amount of a cold receptor stimulant, said stimulant comprising one or more *p*-menthane diols as defined in claim 1.

75 6. A tobacco preparation comprising tobacco impregnated with an effective amount of a cold receptor stimulant, said stimulant comprising one or more *p*-menthane diols as defined in claim 1.

80 7. A toothpick impregnated or coated with an effective amount of a cold receptor stimulant, said stimulant comprising one or more *p*-menthane diols as defined in claim 1.

85 8. A comestible composition comprising an edible base, a flavourant or colourant, and at least one of the following:

2,3-*p*-menthane diol;
2,6-*p*-menthane diol;
2,5-*p*-menthane diol;
3,5-*p*-menthane diol;
3,9-*p*-menthane diol.

90 9. A beverage comprising a potable base, a flavourant or colourant, and at least one of the following:

2,3-*p*-menthane diol;
2,6-*p*-menthane diol;
2,5-*p*-menthane diol;
3,5-*p*-menthane diol;
3,9-*p*-menthane diol.

95 10. A lotion comprising an aqueous, alcoholic or aqueous-alcoholic carrier, an adjuvant selected from the following: a colourant, an antiseptic or an odourant, and a cold receptor stimulant selected from the following:

2,3-*p*-menthane diol;
2,6-*p*-menthane diol;
2,5-*p*-menthane diol;
3,5-*p*-menthane diol;
3,9-*p*-menthane diol.

100 11. A dentifrice comprising an abrasive, a detergent or foaming agent and at least one of the following:

2,3-*p*-menthane diol;
2,6-*p*-menthane diol;
2,5-*p*-menthane diol;
3,5-*p*-menthane diol;
3,9-*p*-menthane diol.

115 12. A toilet preparation comprising an

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- oleaginous base and at least one of the following:
2,3-p-menthane diol;
2,6-p-menthane diol;
5 2,5-p-menthane diol;
3,5-p-menthane diol;
3,9-p-menthane diol.
13. A pharmaceutical preparation comprising an antacid and at least one of the following:
2,3-p-menthane diol;
2,6-p-menthane diol;
2,5-p-menthane diol;
3,5-p-menthane diol;
15 3,9-p-menthane diol.
14. A cleansing tissue comprising a fibrous tissue impregnated with at least one of the following:
2,3-p-menthane diol;
2,6-p-menthane diol;
2,5-p-menthane diol;
3,5-p-menthane diol;
3,9-p-menthane diol.
15. An article or composition comprising tobacco and at least one of the following:
2,3-p-menthane diol;
2,6-p-menthane diol;
2,5-p-menthane diol;
3,5-p-menthane diol;
3,9-p-menthane diol.
16. A cleansing composition containing a surfactant and at least one of the following:
2,3-p-menthane diol;
2,6-p-menthane diol;
2,5-p-menthane diol;
3,5-p-menthane diol;
3,9-p-menthane diol.
17. Compositions according to claim 1, substantially as hereinbefore described in any one of the foregoing examples.

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